K083372

DEC - 8 2009

XIV. 510(k) Summary

Submitter: Satoshi Noake, International Division, BrainBase Corporation, Tokyo, Japan, Phone: +81-3-3778-0745, Fax: + 81-3-3778-4910.

I. Classification Name and Number: Bone Grafting Material, Synthetic. Part 872.3930. Product code is LYC; Class II, special controls.

II. Proprietary Name(s): ArrowBone-β

III. Registration No: 3005488486

IV. Compliance with Performance Standards: No performance standards are applicable. However we followed "Class 11 Special Controls Guidance: Document: Dental Bone Grafting Material Devices", issued April 28, 2005 ArrowBone-β meets ASTM F 1088 "Standard Specification for Beta-Tricalcium Phosphate for Surgical Implants. ArrowBone-β meets ISO 10993 for biocompatibility and ISO 11137:1995, Sterilization of Health Care Products, requirements for validation and routine control, radiation sterilization. A risk analysis was prepared using ISO 14971:2000, "Application of risk management to medical devices."

V. Description of the Device: ArrowBone-β consists of high purity Tricalcium Phosphate Ceramics of which the Ca/P ratio is 1.50. It is manufactured by a validated manufacturing process which guarantees pure-phase materials depending on the sintering temperature. This process is illustrated in Appendix I. Basically, it involves the well-established methods of wet synthesis from phosphoric acid and calcium hydroxide in dilute solution, spray drying to make spherical aggregates, calcination of the aggregates, x-ray diffraction analysis/identification of impurities, removal of fines by sieving, and molding of the particles into porous granules. These are then sintered at the selected temperature for the product which incinerates and removes the binder, hydroxypropyl cellulose, for which the specifications are shown in Appendix 1.6.

The chemical composition of this material is shown. It can be identified by x-ray powder diffraction analysis as pure-phase beta-Tricalcium Phosphate Ceramic in ArrowBone-β. The diffraction analysis is provided.. The identifying peaks as shown on these patterns for β-tricalcium phosphate are indicated by open circles. These data show that the crystalline structure of ArrowBone-β is pure-phase beta-Tricalcium Phosphate

VI. Labels and Labeling: Draft labels for ArrowBone-β are provided, as are detailed instructions for use, warnings and contraindications.

VII. Substantial Equivalence: ArrowBone-β is substantially equivalent to several synthetic calcium phosphate materials. ArrowBone-β is nearly identical to Cerasorb Dental, Cerasorb M Dental, and CeraSorb P, which were cleared by Curasan AG in K051443, since these (as well as Arrowbone-β) consist of pure-phase Beta-Tricalcium Phosphate with a phase purity of more than 95% and comply with ASTM F 1088-04. ArrowBone-β differs only from Cerasorb products in its granular form in that the ArrowBone-β particles are of a porous spherical nature where as the Cerasorb forms are presented in various shaped porous particles including spherical. These synthetic products were cleared by the FDA in PMA800035 so they are well-established for dental use. Because they are synthetic they do not pose a risk of potential allergic reactions and are neither locally nor systemically toxic.

An extensive animal implantation study of ArrowBone-β was recently conducted by independent scientists at the Tokyo Medical and Dental University (See Section VIII. Animal Studies below for a review of the study). These scientists point out that many studies have shown that tricalcium phosphate is a biodegradable ceramic and useful as bone growth material. These observations demonstrate the biocompatibility and biodegradation of TCP, which was absorbed and replaced by new bone. These are the prime requirements of effective bone growth materials and show this device is substantially equivalent to currently marketed synthetic dental bone growth materials, and nearly identical to Ceresorb cleared in K051443.

ArrowBone-β is also substantially equivalent to Bioresorb Macro Pore, cleared by Oraltronics in K050260. We note that Curasan Cersorb, cleared in K014156 was cited in K050260 as substantially equivalent to Bioresorb. Ceresorb has a surface area of 0.17, Bioresorb has a surface area of 0.78 ($m^2.g^{-1}$) almost 4.6 times as large. The surface area is 0.352 ($m^2.g^{-1}$) for ArrowBone-β. This is well within the range between Cerasorb and Bioresorb. The properties of ArrowBone-β are compared to Bioresorb and Cerasorb in Table 1. All are of interconnecting porous material with varying degrees of porosity and other physical characteristics. We believe this is more evidence of the substantial equivalence of ArrowBone-β to Bioresorb and Cerasorb.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. This product has the same Indications for Use as predicate devices:

Intended for use in reconstruction of natural or surgical periodontal defects of the oral and maxillofacial region, including sinus floor elevation and augmentation of the alveolar crest.

Intended for filling into the site of a bony defect in combination with patient blood, autologous bone, membranes or sterile saline after removal of cysts or surgical removal of retained teeth.

2. The technological characteristics for this product are similar and in many cases nearly identical with those of the predicate devices and those currently on the market They are fine powders, relatively inert, biocompatible and previously used for periodontal purposes.

3. Descriptive information provided shows that the materials from which this device is made are well-established and well understood in the industry and among professional users.

4. The FDA "Decision-Making Process" chart was used and appears in Appendix VIII.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC - 8 2009

BrainBase Corporation
C/O Dr. H. Neal Dunning
President
Neal Dunning Associates
26420 Summer Greens Drive
Bonita Springs, Florida 34135

Re: K083372
Trade/Device Name: ArrowBone-β
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: November 23, 2009
Received: November 24, 2009

Dear Dr. Dunning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

XII.1 Indications for Use

510(k) Number: K083372

Device Names: ArrowBone-β

Indications for Use:

Intended for use in reconstruction of natural or surgical periodontal defects of the oral and maxillofacial region, including sinus floor elevation and augmentation of the alveolar crest.

Intended for filling into the site of a bony defect in combination with patient blood, autologous bone, membranes or sterile saline after removal of cysts or surgical removal of retained teeth.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Betz DDS for Dr. Kevin Mulvey
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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